UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC

EXHIBIT INDEX

PLAINTIFFS' RESPONSE TO DEFENDANTS C.R. BARD, INC.'S AND BARD PERIPHERAL VASCULAR, INC.'S MOTION TO EXCLUDE THE OPINIONS OF DAVID GARCIA, M.D. AND MICHAEL STREIFF, M.D.

Exhibit 1	Garcia Deposition Excerpts 6-21-17
Exhibit 2	Streiff Deposition Excerpts 7-12-17
Exhibit 3	Brauer Deposition Excerpts 8-2-17
Exhibit 4	DeCant Deposition Excerpts 5-24-16 (**FILED UNDER SEAL**)
Exhibit 5	DeFord Deposition Excerpts 6-2-16
Exhibit 6	Ganser Deposition Excerpts 10-11-16
Exhibit 7	Tillman Deposition Excerpts 8-4-16
Exhibit 8	Moritz Deposition Excerpts 7-18-17

EXHIBIT 1

Deposition of:

David Garcia , M.D.

June 21, 2017

In the Matter of:

In Re: Bard IVC Filters Products Liability

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MR. JOHNSON: Form objection.

A. I think some of the information in those documents may be pertinent to my global opinions.

Q. (By Mr. Lerner) Okay.

A. Yeah.

Q. After reviewing these documents, did you request any additional documents from the plaintiffs' counsel?

A. No.

Q. All right. So if we look at all the documents that you were relying upon to form your opinions in this case -- we looked at your reliance list, which is Exhibit-2. We have Exhibit-2A, which are six internal company documents. You mentioned the Kessler report, some IFUs. You also mentioned you reviewed Dr. -- Mr. Ganser's deposition.

A. (Witness moves head up and down.)

Q. Is that the entirety of the materials that you reviewed, that you're relying upon, for your opinions in this case?

A. I'll just make the one qualifier that -- I mean, I have an extensive background, knowledge, and clinical experience that of course influences my opinion. But with respect to specific documents/publications, yes, that would be a

comprehensive list.

Q. Okay.

A. Yeah.

MR. JOHNSON: Can I interject one thing, Matthew?

MR. LERNER: Yeah.

MR. JOHNSON: It'll probably save us some time. There's one article that he actually provided to us, that's not on this list --

MR. LERNER: Okay.

MR. JOHNSON: -- recently.

MR. LERNER: Do you know what that article is?

MR. JOHNSON: It's by Cook, I believe.

A. I think it's Rogers, is the first author. But it's JAMA Surgery, 2017. I'm pretty sure it was published subsequent to the production of this report, or right around the time the report's being produced.

Q. (By Mr. Lerner) And based on that article, were you planning to do any further supplementation of your report?

A. Probably not, no. And actually I should say Rogers is -- Fred Rogers is the senior author. He's the last author of that paper. So you might be right, Joe, that Cook might be the first author.

Q. All right. So I think with that Fred Rogers

A. We met from nine till about three, so six hours.

Q. And did you charge just for six hours, or you're charging for the entire day?

A. I'm going to just charge for six hours, but I also did a little bit of prep time last night and early this morning -- probably another couple of hours worth that I'll charge for.

Q. Okay. So outside of your prep work with counsel for the deposition, we're still looking at about 25-30 hours total time for you to submit your report?

A. Yes.

Q. And does that include the amount of time you spent on the Jones case?

A. Yes, mm-hmm.

Q. Okay. As far as how you spend your time for those 30 hours, you don't have a breakdown of those -- that time?

A. No. I mean, if what you mean by that is, did I submit this number of hours reading materials and this number of hours talking to lawyers and this number of -- no.

Q. Okay. So how do you track your time then, in order to submit your time?

A. I use an app on my phone called Gleeo Time

Q. Okay. And you've never removed an IVC filter?
A. Neither one.
Q. Okay. And the focus of your scholarship has primarily been on what?
If someone were to ask you -- "This is the area that I focus in" -- what would you say?
A. I usually answer -- laypeople -- that blood clots and blood thinners.
Q. Okay. And because -- that you treat people that sometimes have blood clotting disorders, sometimes you interact with people that may need -- may need to be treated with IVC filters?
MR. JOHNSON: Form.
A. I would say that, very rarely, there are situations where I have recommended an IVC filter.
Q. (By Mr. Lerner) Okay. Do you still recommend IVC filters today?
A. I recommended one just last month.
Q. Okay. And what was the situation for that?
A. A patient who suffered pulmonary embolism, and shortly after that suffered intracranial bleeding while on anticoagulant therapy. And I considered that the risk of continuing anticoagulation in that patient was prohibitive.
And the risk of additional thrombosis was high

enough that, although I have serious doubts about the magnitude of the benefits of filters, I felt that -- that the possibility that the filter could be beneficial to that patient outweighed its various risks. But we had a long discussion with her and her family about that.

Q. Okay. And then tell me about that a little more. When you are involved in the decision -- you are involved in the decision for patients about whether to recommend or not an IVC filter?

A. Very often.

Q. Okay. But you're often, I would imagine, talking to other physicians who are also part of that decision-making process?

A. I would say so. Although because of my background and expertise -- at least in my own institution -- I would say there's a lot of deference to my opinion.

Q. Okay. Do you have any protocols in place at your institution about the placement of IVC filters?

A. I don't know of any, no.

Q. Okay.

A. Any written protocol, no.

Q. And there are IVC filters that to this day are being placed in your facility --

A. Yes.
Q. -- in your hospital?
When you are part of the decision-making process for placement of IVC filters, are you involved in making recommendations about whether somebody has a permanent filter or an optional filter that can be retrieved?
A. I would say that the default recommendation nowadays -- in those rare cases, where I would recommend a filter -- is to place a retrievable one.
Q. Okay. And why is that?
A. Because the sooner we can take the filter out, the less risk I think it has.
Q. Okay. So, when was the last time you recommended that a permanent filter be placed?
A. I can't remember.
Q. Okay. Do you think you've ever recommended that a permanent filter be placed?
A. Not when I was in any position of authority, no.
Q. Okay. And to this day you still wouldn't -- you would -- Strike that.
Your preference in recommending filters is recommending an optional filter, correct?
MR. JOHNSON: Form.

Q. (By Mr. Lerner) And are you aware that there's guidelines out there by trauma surgeons that -- that would suggest use of an IVC filter in that situation?

A. Yes --

MR. JOHNSON: Form.

A. -- I'm vaguely aware of such guidelines.

Q. (By Mr. Lerner) Okay. So, again, it goes back to the notion that there is differences of opinion among doctors in different specialties or even in the same specialty about the use of IVC filters; is that fair?

A. Yes.

Q. You have -- you have your opinions about the use of IVC filters, and there's others out there that have differences of opinions about -- than you, correct?

MR. JOHNSON: Form. Vague.

A. I'm -- I'm sure there are people who have different opinions from mine. And the guidelines you cited would -- would suggest that there's at least some trauma surgeons who do.

Q. (By Mr. Lerner) And -- well, I'm going to have some more specific questions about that a little bit later.

When patients are being prescribed IVC

filters -- patients of yours -- are you involved in the consent process for that?

MR. JOHNSON: Form.

A. Only if I am the doctor who is recommending the filter.

Q. (By Mr. Lerner) Okay.

A. I mean, I recently saw a patient who was planned for a surgery to remove a bunch of blood clot from her lungs and had been advised to have a filter placed by the surgeon who's going to do the operation. And I advised her against it. So I mean, yes, I am involved in that sort of informed decision-making.

Q. Okay. But is it typical for the person that's actually placing the filter to be the person that gets the consent from the patient?

A. Well, I think -- I mean, I think the interventional radiologist or the person who's actually deploying the filter has a duty to inform the patient about the risks and benefits of the specific procedure itself.

So you might have bleeding on the site where we put the catheter, you might get an infection from the fact that we're entering a sterile part of your body. But I actually think that there's a duty of the treating physician to inform the patient about the long-term

risks and benefits, to the extent that he or she can know them from published information.

Q. And then of the 15 or so filters -- or maybe it's less than that -- that you have been involved in recommending over the last 15 years, how many of those would you say that you were part of an actual consent process?

A. Yeah, like I said, I think it'd be closer to half a dozen. And I'm quite confident that I had a -- involved discussion with the patient before all of them.

Q. Okay. And the first time that you think you would have been involved would be somewhere in 2005 or --

A. Maybe a little before that, but in that ballpark.

Q. Okay. And has your practice -- that would be, tell patients about potential complications -- been the same during that entire time?

A. No, I would say it's -- my advice about risks has changed a bit because -- for example, it's probably only in the last 10 years or so that I've recognized -- or that I've come to the conclusion that the rate of thrombosis of the cava itself is probably as high as 5 percent.

And so -- and I've also seen -- I mean, dating

back to when I was a resident, I've personally seen cases of a strut of a filter being in the duodenal lumen, or had colleagues with patients who had a filter and migrated to the heart.

And so based on experience that I've accumulated over the years, as well as published information that I'm aware -- that I've become aware of, is I've focused in this area. I think the nature of my discussion about risk has probably changed.

Q. Okay. You said 5 percent thrombosis. You're saying for -- of all IVC filters -- that having an IVC filter, 5 percent of the time there's going to be thrombosis caused by the IVC filter? Did I hear you --

A. Yes.

Q. -- correct?

A. So -- so to restate it, caval thrombosis -- where the inferior vena cava is occluded by thrombus -- happens in 2 to 6 percent of patients with IVC filters, according to published data. And that is always, in my opinion, the result of a filter. It doesn't just coincidentally happen.

Q. So, that's not specific to a particular filter. You're saying for all filters, that's what the literature shows?

A. Yes.

the relative safety or efficacy could be made based on those observational studies?

MR. JOHNSON: Form.

A. Because as I said -- as I said earlier, observational studies cannot be relied on to determine relative efficacy or safety between two treatment options.

But in this case, what -- I'm merely -- I'm merely gleaning from the observational studies that if you put an IVC filter in 100 people, about five of them will have thrombosed their vena cava over the next one to two years.

I can tell you, from taking care of patients for 20 years and again from other published literature, that event -- IVC thrombosis -- almost never occurs in the absence of an IVC filter.

So, I'm very comfortable in that particular instance concluding from the observational cohort study that there -- that this risk is attributable to IVC filters. And I have a pretty good idea of what the magnitude of the risk is.

Q. (By Mr. Lerner) Okay. All right. Let's go down to the next paragraph here. You say that, "Thus, in order for physicians to make reasonable risk-benefit assessments regarding filters, it's critically important

that manufacturers of IVC filters continuously apprise the clinicians who order and implant IVC filters about their safety profile, performance characteristics, design problems, and internal risk assessments."

So, what are you saying there?

A. Well, I mean, I think this is a -- a statement that could apply to the manufacturer of any device or medication that's going to be prescribed or deployed by a -- by a treating physician. But it's perhaps --

I think we wanted to emphasize it here, because when you have an intervention -- the benefit or efficacy of which is highly questionable or poorly established -- ensuring that the doctors who are choosing to use it know as much detail as possible about its risks, has heightened importance.

Q. What does that mean in practical terms? Are you suggesting that every time there's an adverse event with a medical device, that the manufacturer should be reporting that to every physician that uses the device?

A. No. I'm not trying to suggest an unreasonable burden on any corporation. But I think -- but I do think that -- I think there's -- I do think there's a strong requirement that --

I guess, I think that a company should have a perhaps even lower than average threshold to track and

report risk when a -- when a device or intervention has poorly established or -- or unestablished benefit.

Q. Are you familiar with the FDA regulations about what information can and cannot be provided to physicians by manufacturers?

A. I'm not.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) And you wouldn't want manufacturers providing unreliable information, correct?

A. No, I wouldn't.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) And you wouldn't want manufacturers to be providing incomplete information?

MR. JOHNSON: Form.

A. Well, I think -- I mean, I think that the challenge there is -- who's making the judge to whether it's complete or incomplete and -- and what context it's being provided.

I certainly wouldn't want a manufacturer to be providing information that would mislead a physician in either direction, over- or underestimating the risk.

Q. (By Mr. Lerner) Yeah. You want manufacturers providing you with reliable scientific information, correct?

MR. JOHNSON: Form.

judgment.

Q. (By Mr. Lerner) Is there any other manufacturer, that you're aware of, that's providing you the information that you say should be provided by manufacturers?

A. Well, I can't think of one. But, I mean, I also can't think of a -- of an intervention or a device that is so widely used, at least in my sphere of practice, with so little high-quality evidence for its benefit.

Q. What do you mean here when you say that companies should be providing internal risk assessments? What does that mean?

A. Well, the -- I think what -- what we intended to say there with Dr. Streiff is that if a company makes an internal -- what's originally an internal determination that a device or product is associated with a particular risk that has not been publicly disclosed, then -- then they need to publicly disclose it -- I mean, whether it's to regulators or to practicing physicians. But somebody needs to know about it.

Q. In the next sentence you say, "In addition, filter manufacturers have a key obligation to report the experiences of other physicians who have reported

potentially receive, you know, all or many reports of complications from a much wider scope of observation, if you will.

And if a company is getting reports from far and wide of complications -- which are maybe happening infrequently at any given institution, but with some frequency in the world at large -- they're the only entity that has the ability to provide that perspective to an individual physician, who is him or herself just only able to focus on what's going on in their immediate surroundings.

Q. (By Mr. Lerner) Are you aware that reports of complications are reported to the MAUDE database?

A. I'm aware of the MAUDE database. But I believe that experts like Dr. Kessler and others, who are much more familiar with regulatory history than I am, believe or have evidence to think that there's underreporting when it comes to the MAUDE database.

Q. But individual adverse events themselves, like case reports, they're on the lowest end of the spectrum of the hierarchy of scientific evidence, correct?

A. That is true. In isolation, a case report is at the lowest end.

Q. I mean, even if not -- not in isolation, if you have various adverse events, spontaneous reports,

regulatory affairs that: 'Transparency in matters that affect patient safety should be embraced as a primary corporate obligation.'"

So you read the one deposition of Chris Ganser, and you --

A. Right.

Q. -- you decided on your own to add this one sentence here to your report?

A. I mean, I decided in -- in conjunction with Dr. Streiff, in the various back-and-forth discussions we had, yeah.

Q. So, are you implying here that somehow -- that Bard has not been transparent about the safety profile of its IVC filters?

A. Well, I think the -- I mean, I don't consider that to be the principal opinions in -- that I have in this matter, but I -- but I am concerned by some of the things that I've been shown by plaintiff counsel.

I mean, just -- and if you -- I can cite a couple of examples, but -- but, yeah, I do have some concern that Bard is not completely transparent.

Q. Okay. And the reason why you have that concern, is it based on the Dr. Kessler report that you reviewed?

A. That's a big part of it, yep.

(Exhibit-11 marked for identification.)
MR. JOHNSON: I don't need one, Matthew.
MR. LERNER: I figure you have the copy of the report in front of you.
MR. JOHNSON: I do.
Q. (By Mr. Lerner) All right. So you have a copy of Exhibit-11, which is your addendum?
A. I do.
Q. Okay. Did you read Dr. Kessler's report?
A. I've read it, yes.
Q. Did you read it in its entirety?
A. At some level, I've read it in its entirety.
Q. How many pages is that report, do you recall?
A. In the hundreds.
Q. And you read all those pages in detail?
A. I would say there were some pages I read much less closely than others, but --
Q. Okay.
A. -- I've looked at the text of every page in some form or fashion.
Q. And what was the reason why you read his report?
A. Because, as I recall -- again in discussions with counsel and Dr. Streiff, we -- it was felt that it would provide important background information.

Q. So in drafting your addendum and kind of essentially regurgitating what Dr. Kessler found in his report, did you attempt to be as accurate as possible in describing Dr. Kessler's findings?

A. I did.

MR. JOHNSON: Form.

Q. (By Mr. Lerner) You didn't try to modify in any way Dr. Kessler's findings?

A. That was certainly not my intent, no.

Q. (By Mr. Lerner) And so you didn't change any of the findings from Dr. Kessler's report, in part of the --

A. No.

Q. -- addendum there?

A. No.

Q. So you included seven numbered paragraphs, repeating what Dr. Kessler himself says in his own report?

A. Yes, because the -- while there's publicly available evidence of IVC filter risks that you and I have discussed earlier in today's deposition, this -- these elements of Dr. Kessler's report, I thought, highlighted additional risks associated with the Bard product in particular, that were not necessarily publicly known about or available to practicing doctors

and -- and -- but were relevant in the overall risk/benefit discussion that -- that my report entailed.

Q. Okay. So you don't say anything in your addendum about Dr. Kessler's findings, that he himself doesn't say in his own report, true?

A. Correct.

Q. Okay. In other words, you are repeating what Dr. Kessler found, without changing anything?

A. Essentially, yes, in the context of my report -- or to add context to my report with Dr. Streiff, yes.

Q. But Dr. Kessler's findings do not factor into your actual analysis in this report, true -- your whole report that we just went through?

A. Well, only -- only in that they -- only to the extent that they provide additional information about risk, which we haven't talked about much today. But the risks associated with IVC filters, yeah, because that's a major subject of my report -- is risk benefit, yeah.

Q. No one asked you, as part of your analysis, to perform a regulatory analysis?

A. No.

Q. And it's not necessary for you to conduct any kind of regulatory analysis to reach the opinions that you set forth in your expert report; is that true?

A. True.

Q. Yeah. And you understand that Dr. Kessler prepared this report for use in litigation?

A. Yes.

Q. Okay. Can you describe the methodology that Dr. Kessler employed in reaching his opinions?

A. No.

Q. Okay. Did you independently verify Dr. Kessler's methodology?

A. Not in any great detail. I mean, for example, I've looked at the paper by Murray Ash and made sure that my own assessment of that paper was consistent with Dr. Kessler's.

And I read the report provided to Dr. Kessler by Dr. Betensky regarding analysis of adverse reports, just to generally make sure I shared his conclusions. But -- but beyond that, no.

Q. Okay. Have you reviewed any Bard FDA submissions or correspondence?

A. Not that I recall.

Q. Did you independently review and assess the reliability of the underlying data that Dr. Kessler relied on?

A. Not beyond what I just told you.

Q. Okay. Did you check or test any of the

Q. -- correct?

So you don't know if there are other facts or data out there that Dr. Kessler or Dr. Betensky admitted, that may affect whether you agree with their opinions?

A. No, I -- I don't. But I would -- again, I would just say that I considered this addendum about Kessler's report to be information that strengthens the rest of my report with Dr. Streiff. But my report with Dr. Streiff would still stand, even independent of all this information.

Q. So, you read Dr. Kessler's report. You read Dr. Betensky calculations. You didn't perform any independent analysis, but simply kind of agreed with their analysis?

A. Correct. I guess one way you could say is that, assuming their analysis is true, it just strengthens the conclusions of my report.

Q. Okay. And how so?

A. Because their -- the facts stated in -- or the information stated in this addendum only further highlights the risks of IVC filters, beyond what I could have done using publicly available peer reviewed information that's cited in my report -- the rest of my report.

loop and that they were going to try to do some sort of surgery to address it. But I -- but I actually don't remember the specific outcome of that.

Q. Okay. If her doctors have not determined what the cause of her GI bleed is or has been, would anticoagulants be appropriate?

A. Possibly. So patients who have GI bleeding and undergo a thorough evaluation, including endoscopy and usually a capsule camera exam of the small intestine and who remain free of bleeding for some period of time -- usually a week or two -- it's reasonable to re-challenge them with anticoagulation.

Q. And so do you know whether those situations happened here?

A. I don't know.

Q. Okay. So, given that, you can't say today whether she would be an appropriate candidate for anticoagulation?

A. I can't -- I think it's fair to say I can't fully assess the risk of anticoagulant therapy in her, because I don't have some of those details, yeah.

Q. Okay. All right. Based on your report, you have an understanding that she has a fragment of one of the struts from her filter that remains in a branch of one of her pulmonary arteries?

presence of a foreign body in a pulmonary artery branch represents a permanent, significant risk factor for the development of in situ thrombosis."

Did I read that correctly?

A. You did.

Q. Okay. Have you ever personally diagnosed a fractured filter strut, causing thrombosis?

A. No.

Q. Okay. Have you ever seen a fractured filter strut, causing thrombosis, reported in the medical literature?

A. No.

Q. And there are other risk factors for the development of in situ thrombosis, correct, beyond what you're saying here is a filter strut?

A. Yes.

Q. Can you describe some of the other risk factors for development of in situ thrombosis?

A. Sure. Compression of a vessel, presence of central venous catheter, prosthetic mechanical heart valve would be a few.

Q. And then in Mrs. Jones's situation, her particular medical situation, can you describe any conditions that she has that make her at risk for the development of in situ thrombosis?

MR. JOHNSON: Form.

A. Well, the -- I mean, the personal history of venous thromboembolism is a risk factor to develop venous thromboembolism again in the future, particularly if the original clot was unprovoked. And I don't recall, in Ms. Jones's case, whether hers was or not.

But I guess -- I guess it's important to say that venous thrombosis is almost always a multi-causal event, meaning there's usually more than one contributing factor to the formation of a blood clot. We can't always identify what they are, but --

Q. (By Mr. Lerner) Right.

A. -- it can be more than one, and it often is.

Q. Are you aware of anything in the medical literature that supports the finding that a fractured fragment has contributed to causing thrombosis?

A. No, I'll be -- I'll be extrapolating, though, from data that I think does establish that an intact filter promotes thrombosis formation.

Q. But an intact filter, the size of that is very different from a fragment --

A. Yes.

Q. -- from one of the arms or legs?

A. But I'm not aware that surface area or size has any correlation with thrombosis risk, when it comes

Q. Okay. And so you cannot state with a reasonable medical certainty that Mrs. Jones' blood flow in her pulmonary artery is turbulent because of the filter strut?

MR. JOHNSON: Form.

A. Don't agree. I mean, I -- I do -- I have a reasonable degree of medical certainty that there is turbulent blood flow around that strut.

Q. (By Mr. Lerner) So you've not examined the strut, you've not examined any of her imaging. And without doing that, you believe that you can say to a reasonable degree of medical certainty -- more likely than not -- that Mrs. Jones' blood flow in her pulmonary artery is turbulent because of the filter strut?

MR. JOHNSON: Form objection. The question's also --

A. I do. But more importantly -- more importantly, I can say to a reasonable degree of medical certainty that that filter strut being there -- irrespective of by what mechanism -- is putting Ms. Jones at increased risk of thrombosis in that -- at that -- at that site and distal to it.

Q. (By Mr. Lerner) And what is that based on?

A. The observations of IVC filters promoting thrombosis in randomized controlled trials, as well as

in observational cohort studies, as well as the observation that foreign bodies -- examples of which I cited to you earlier -- catheters, prosthetic mechanical heart valves -- can promote -- do promote thrombosis.

Q. Right. But the situations in the literature you cited dealt with filters -- whole filters; they didn't deal with individual struts. So, those articles don't really support your position?

MR. JOHNSON: Form.

A. I think they do. I mean, I -- I -- I guess that's -- we can agree to disagree about that. But, I mean, I'm very comfortable in saying that -- that having a foreign body sitting in one's pulmonary artery is going to put a patient at risk for thrombosis.

Q. (By Mr. Lerner) Again, though, you can't point to any specific literature relating to filter struts in the pulmonary artery that would support your position?

MR. JOHNSON: Form.

A. No, I can't.

Q. (By Mr. Lerner) And you cannot state within reasonable medical certainty that Mrs. Jones' blood flow in her pulmonary artery is turbulent because of the filter strut, such that she will develop thrombosis?

MR. JOHNSON: Form objection. Misstates --

A. Well, I --

MR. JOHNSON: -- his testimony already.

A. Yeah, I would -- I would say that the -- again, irrespective of the mechanism, I'm confi -- it's my expert opinion that she is at increased risk to develop in situ thrombosis, as well as embolization distal to the site.

Q. (By Mr. Lerner) You say that she --

A. Because of the presence of the filter strut.

Q. You say that she's in an increased risk. That doesn't mean that she's more likely than not to develop thrombosis because of the strut, correct?

MR. JOHNSON: Form.

A. Correct, yeah.

Q. (By Mr. Lerner) Your second explanation in your report is that "the body has a biochemical response to a foreign object exposed to the circulating blood. This response promotes the formation of thrombus on the foreign body (in this case, the filter fragment.)

"Thus, the mere presence of the filter in a pulmonary artery branch can result in a hyper-coagulable condition which promotes the creation of a local thrombus." Did I read that correctly?

A. You did.

Q. So, what is the basis of your opinion that a

biochemical response to a filter fragment exposed to a circulating blood promotes the formation of thrombus on the filter fragment?

A. So, a var -- I mean, a variety of foreign objects again -- and I've cited clinical examples to you of those -- when they're exposed to circulating blood, they activate factor XII, which is one of the clotting proteins that are involved in the so-called contact activation or intrinsic activation pathway.

And that triggers a chain -- a series of chain reactions that ultimately can lead to the formation of a blood clot. And it's entirely stimulated by contact with foreign surfaces. And I have no reason to think that a filter fragment would be an exception to a rule that's certainly followed by many other foreign bodies.

Q. Are you aware of any literature that supports your position that in this situation, where a fragment -- a filter fragment -- that the body -- specifically Mrs. Jones' body would likely have a biochemical response to the strut?

MR. JOHNSON: Form.

A. No.

Q. (By Mr. Lerner) Okay. And if the strut is endothelialized, as you believe it is, do you believe it is exposed to circulating blood?

she's likely going to trigger formation of a blood clot?

A. Well, I mean, I think she's at much higher ri -- whether it's because of an injury to the blood vessel wall or whether it's because of turbulence or whether it's because of a direct biochemical stimulus, she is at increased risk to form a clot, over and above what she would be if this fracture weren't in her -- if this fractured strut were not in her pulmonary artery.

Q. Are you able to quantify what that risk is, that increased --

A. No.

Q. -- risk is?

And then are you able to point to any literature or scientific studies that would help quantify that she's at an increased risk?

A. No, other than again extrapolating from what we know about intact filters.

Q. And, then, doesn't the -- Strike that.

If the fragment has in fact at some point caused injury to the inner wall, the pulmonary artery, do you know when that would have occurred?

A. I would assume shortly after the frac -- the -- it fractured and migrated there.

Q. And wouldn't the wall that -- pulmonary artery then heal?

EXHIBIT 2

Deposition of:

Michael Streiff , M.D.

July 12, 2017

In the Matter of:

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I've seen as part of -- I think Dr. Garcia's deposition, there's some in there; yeah.

Q. Okay. Outside, I guess, of the IVC filter litigation and outside of Dr. Kessler's report and reviewing Dr. Garcia's deposition and the exhibits, you have not previously ever reviewed internal, internal company documents?

A. No.

Q. And you are not an FDA expert?

A. No.

Q. And you're not holding yourself out as an expert as, into FDA compliance?

A. No.

Q. You also have not worked in any company in post-market surveillance --

A. No.

Q. -- for -- okay. So you're not holding yourself out as an expert in post-marketing surveillance?

MR. O'CONNOR: Form and foundation.

THE WITNESS: No.

BY MR. LERNER:

Q. Do you have any experience developing warnings for IVC filters?

A. Warnings?

Q. Warnings.
A. No.
Q. No. And you're not offering -- strike that.
You're not claiming to be an expert as to warnings for medical devices or IVC filters?
MR. O'CONNOR: Object to the form of the question.
THE WITNESS: No.
BY MR. LERNER:
Q. Have you ever had your expert opinion excluded by any court, to your knowledge?
A. No.
Q. And you've never -- in all of the cases we've talked about, you've never attempted to offer an expert opinion in anything other than medical-related opinions; is that fair?
A. That's true.
Q. All right. Now, I'm going to start focusing more on the medicine now.
A. Okay.
Q. Are you still doing okay with time?
A. Oh, yeah. Yeah. I'm fine.
Q. Okay. Can you describe what the difference between a DVT is and a pulmonary

Q. Okay.
A. -- on those documents.
Q. So that's --
A. And then we went on further to make an -- it was, you know, we ought to make an addendum on, that goes into, more in detail about that report, or at least several points from it.
Q. Okay. So the statement here that in order for physicians to make reasonable risk-benefit assessments regarding, regarding the filters, it is critically important that manufacturers of IVC filters continuously apprise the clin-, clinicians who order implant IVC filters about their safety profile, performance characteristics, design problems, internal risk assessments, that was a personal opinion that, that you and then Dr. Garcia had after reading the Dr. Kessler report?
A. That is exactly --
MR. O'CONNOR: Object to the form.
THE WITNESS: Sorry. That's, that's right. That's something we -- that's not something coming from the literature. That's coming from after seeing that report large -- yes.
BY MR. LERNER:

Q. And, and you are not basing that statement on any kind of FDA regulation standard or some law. That's just kind of a personal opinion?

A. Yeah, that's after looking at those documents.

MR. O'CONNOR: Object to the form of the question.

THE WITNESS: Sorry.

BY MR. LERNER:

Q. And, and when you say that manufacturers should continuously apprise physicians of certain information, again, that's not based on any particular regulation, standard or law. It's based on your personal opinion?

MR. O'CONNOR: Form.

THE WITNESS: True.

BY MR. LERNER:

Q. And when you use the term continuously apprise, are you saying that manufacturers should be providing information to doctors how often?

A. I would say that if you have a -- you know, obviously, I'm -- this is -- I'm an outsider. The whole FDA, the vice pros, you know, approval process or drug approval process, because I haven't been involved with that either, but if you have --

Q. And am I right that you -- I thought Dr. Garcia said this, but maybe I misremembered, that you actually were the one that took the draft of these?

A. I may have -- I may have, you know -- I guess I may -- yeah, I may have done that. Yeah.

Q. Okay.

A. I can't recall if I did it all or -- yeah.

Q. In the beginning of the deposition, I asked you about evidence-based medicine --

A. Um-hum.

Q. -- and is it important to you as a physician, as an evidence-based physician to review both sides when there's conflict in opinions about things?

A. True. Yeah.

MR. O'CONNOR: Object to the form of the question.

BY MR. LERNER:

Q. And you also in response to one of my questions today, you said it was important to be fair and balanced, right?

A. Yeah. Of course, yeah. Look at all of the data and make your decision --

Q. So, in other words, you're repeating in your report some of the findings that Dr. Kessler has found without changing anything?
A. Right. I think it's a summary of what we read in the, in his, his report.
Q. But Dr. Kessler's findings do not factor into your, the, the main opinions you're offering in this, in this case?
A. Sorry.
Q. Sorry. Dr. Kessler's opinions do not factor into the medical opinions that you're offering in this case?
MR. O'CONNOR: Form.
THE WITNESS: Well, I mean, I think that when we saw those, I think that was, certainly that was -- I think the data he had in his report I think were, we found were troubling and would make one consider whether there were events that had already occurred in, you know, in papers.
Like the Nicholson papers, for instance, where they had a lot of fractures, this kind of would support what they were saying. The Nicholson paper only focused on G2 and recovery filters and frac-, you know, frac-, you know, filter-like fractures and stuff like that, but as these data

would suggest, oh, is that what -- is there a connection there?

I think that's what I think both Dave and I both thought of when we, we saw it. You have the Nicholson data out there, and then you have this. It's like, Wait a second. This is -- was this known before? I think that's what came up in our minds when we read the Kessler report.

BY MR. LERNER:

Q. Okay. And the Nicholson, you're talking about the New York Hospital article?

A. Yeah. Exactly. Yeah, yeah, yeah, yeah.

Q. Are you aware that there was a correction to that article?

A. No. Actually, I don't think I saw that.

Q. So you were never aware there were several inaccuracies within that article?

A. No, but I'd love to take a look at it and see what the inaccuracies were.

Q. But no, no one has ever told you that there are several --

A. No, I didn't see that.

Q. Let me finish my question.

A. Oh, I'm sorry.

Q. So no, no one ever told you that there

A. Yes.
MR. LERNER: Objection to form.
BY MR. O'CONNOR:
Q. Did his report contain actual excerpts or quotes of documents?
A. Yes, it did.
MR. LERNER: Objection to form.
BY MR. O'CONNOR:
Q. And did that include internal documents produced by Bard?
MR. LERNER: Objection to form.
THE WITNESS: Yes. He had quotes from different employees of Bard, some which had, some of the employees had concerns about the, the performance tests and also data, you know, data from patient events.
BY MR. O'CONNOR:
Q. When you reviewed Dr. Kessler's report and relied on statements and facts from his report, were you satisfied that the information you relied upon from his report was reliable and trustworthy?
MR. LERNER: Objection to form.
THE WITNESS: Yes. I mean, I think that he has data to back up all of the con-, the conclusions he made in his report. They're, you

know, what looked like excerpts from internal documents showing, you know, as I said before migration testing and, and data from comparison with the different filters, cranial and caudal migration, and that the G2 and recovery filters had a greater tendency to that than comparators.

BY MR. O'CONNOR:

Q. Now, when formulating your opinions in this case, first of all, as a hematologist in your, in your position in the medical community, including your position at Johns Hopkins Hospital, do you keep yourself regularly apprised of the medical literature, research and studies that pertain to issues of DVT, PE, clotting and IVC filters?

MR. LERNER: Objection to form.

THE WITNESS: Of course. I subscribe to a number of different articles. With the Welsh Medical Library, I have like 20,000 articles online, and I can -- you know, so I get emails. I have context, contents to journal, you know, table of contents sent to me of probably 30 journals that I review, so yeah.

BY MR. O'CONNOR:

Q. And when you were arriving, preparing

community?

A. Yeah.

Q. Is it an expectation in the medical community that companies that provide medical devices, that they will put patient safety, patient safety first and paramount?

A. Of course.

Q. In this case when you arrived at opinions, including opinions based upon the information from Dr. Kessler, were those opinions based upon what you understand and know are the expectations of doctors in the medical community?

MR. LERNER: Objection to form.

THE WITNESS: Certainly. I mean, when I read his report, I was reading it as, you know, a hematologist, you know, reading, looking at data and, and assessing what I, what I had in there and then comparing it to what I know from the literature, having read the literature.

BY MR. O'CONNOR:

Q. And based upon your review of all of the information in this case, did you arrive at an opinion whether the Bard filters met the reasonable expectations of medical doctors in the community?

MR. LERNER: Objection to form. Outside

EXHIBIT 3

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	) No. MD-15-02641-PHX-DGC

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF CHRISTINE L. BRAUER, Ph.D.

WASHINGTON, D.C.

WEDNESDAY, AUGUST 2, 2017

9:07 A.M.

Reported by: Leslie A. Todd

the hesitancy in my voice is coming from a difference in misrepresentation of facts versus maybe not agreeing with his conclusions.

So I'd have to look at specific statements to be able to affirmatively agree with you or disagree with you. Just sitting here today without going through line by line of the report, I cannot do it for you, sir.

BY MR. LOPEZ:

Q Okay. So you can't tell me whether or not there's been misrepresentations in the report as you sit here right now.

A Misrepresentations of facts --

Q Of facts, right.

A -- is the question. Sitting here today, no, I can't say that.

Q Did you look at his -- all of his schedules?

A I looked at a number of his schedules.

Q Are there -- was there anything contained in any of his schedules that were misrepresentations of what are contained -- what he -- what is summarized or what he relates in those schedules as being factual?

A Not that I can recall sitting here today.

Q All right.

A I think that there are certain areas of the report where I disagreed with Dr. Kessler's interpretation or conclusions or how he may have considered certain data.

Q Okay. I asked you about the schedules. That's all I asked you about. Whether or not you -- as you went through the schedules, you're saying, Well, that's not an accurate representation of a document, that's not an accurate representation of a study, that's not an accurate representation of an IFU, that sort of thing.

A An actual -- if you're asking for an accurate representation of certain data, I may have differences of opinion with him. The facts may be the same.

Q Okay. I think I found an answer in there somewhere.

Did Dr. Kessler in his report as he relates to certain Bard documents take any of those documents out of context?

BY MR. LOPEZ:

Q Well, it --

A It's not possible for me to do, sir.

Q Isn't that the most important thing that we should be talking about in this case is what are doctors' and patients' expectations of the safety profile and the risk-benefit profile of the Recovery, G2 and all the other Bard filters, right?

MR. ROGERS: Object to the form.

THE WITNESS: I agree that it's important for a medical device manufacturer to understand healthcare professionals' expectations for performance of a product.

BY MR. LOPEZ:

Q So we know early in the -- the history of the Recovery filter, based on everything we've talked about and what you've reviewed, that the Recovery filter proved to be not as safe as the Simon Nitinol filter when -- when implanted in patients, true?

MR. ROGERS: Object to the form.

THE WITNESS: I think you're stating things in absolute black and white terms. And I

EXHIBIT 4
(Filed Under Seal)

EXHIBIT 5

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

In Re: Bard IVC Filters Products Liability Litigation	:	No. MD-15-02641-PHX-DGC

- - -

June 2, 2016

- - -

Do Not Disclose - Subject to Further Confidentiality Review

- - -

Videotape deposition of JOHN A. DeFORD, Ph.D., taken pursuant to notice, was held at the Hilton Short Hills, 41 John F. Kennedy Parkway, Short Hills, New Jersey, beginning at 9:11 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

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but the decision was made that the product continued to add value and shouldn't be placed on hold.

BY MS. BOSSIER:

Q. Well, if the product had been placed on hold, then you would not have had a retrievable filter on the market. Right?

A. Well, that's -- that's correct, but that -- that wasn't part of the analysis, except that clinicians wanted a device they could retrieve. It wasn't a company decision, well, we're not going to put it on hold because we're selling a retrievable product.

It was the belief and our continued belief that this product added unique, special value and patients' lives were being saved.

Q. Well, physicians wanted a retrievable filter, but physicians, I would assume, and I'm sure that you would agree, wanted a retrievable filter that was safe, correct, and efficacious;

correct?

A. Certainly. The risk/benefit has to be evaluated in every device.

Q. Right. And the doctor needs to be aware of the risks of any device prior to recommending that device for a patient; correct?

A. That's correct.

Q. And we saw earlier that one of Bard's threshold points that they made in this investigation that began in February of 2004 was that they were going to do -- prepare a dear doctor letter to let the doctors know about that single migration event in February of 2004; correct?

MR. NORTH: Objection to form.

THE WITNESS: That -- that was an item that was on the action plan to be developed, yes.

BY MS. BOSSIER:

Q. Because you're telling me that these doctors were clamoring for the

EXHIBIT 6

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

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IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	No. MD-15-02641-PHX-DGC

- - -

OCTOBER 11, 2016

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DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of CHRISTOPHER D. GANSER, held at HILTON SHORT HILLS, 41 John F. Kennedy Parkway, Short Hills, New Jersey, commencing at 9:32 a.m., before Margaret M. Reihl, a Registered Professional Reporter, Certified Realtime Reporter, and Notary Public.

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go to doctors to provide treatment for me.

Q. I know, but you'd want your doctor to have the safety profile, the risk evidence, the effectiveness evidence that exists as to each device so that doctor could make that choice, true?

A. I want the doctor to have --

Q. Sir, is that true? I mean, if it's not --

A. It's true I want the doctors to have as much information as possible to make an informed decision how to use the product.

Q. All patients deserve that right --

MS. DALY: Objection.

BY MR. LOPEZ:

Q. -- for their doctors to be fully informed of all of the potential information about risks and benefits so that the doctors can make an educated choice for the patient, true?

MS. DALY: Object to the form.

BY MR. LOPEZ:

Q. True, sir?

A. Yes.

Q. So did the company tell doctors that in just one month, in January of 2007, that they have a G2

EXHIBIT 7

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

IN RE BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	) No. MD-15-02641-PHX-DGC

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

VIDEOTAPED DEPOSITION OF DONNA-BEA TILLMAN, Ph.D.

WASHINGTON, D.C.

FRIDAY, AUGUST 4, 2017

9:18 A.M.

Reported by: Leslie A. Todd

omitted.

Q Right.

A So we presume that all material facts have been provided.

Q For example, if there was -- well, you read Dr. Kessler's report, right?

A I did.

Q And did you actually look at the -- the documents that he relies upon for purposes of rendering his opinions?

A I reviewed many of the documents that he referenced. I can't say that I reviewed every single one of them.

Q And you had an opportunity to rebut his report in your report.

A I did.

Q And did you look at all his schedules that were attached to his report?

A I did review his schedules, yes.

Q How many hours did you spend reviewing the same materials and the same issues that Dr. Kessler reviewed?

A I don't know how to answer that question the way you phrased it.

Q Can you name or list for me any document or -- from Bard or deposition testimony from Bard that's in his report that you believe that Dr. Kessler -- let's start with misstated?

A Dr. Kessler's report is extremely long, and I -- I could not make any kind of general statement about that.

Q Did he -- was any of the material within his report taken out of context?

MR. ROGERS: Object to the form.

THE WITNESS: Once again, his report is too long for me to make any kind of generalization.

BY MR. LOPEZ:

Q Was it -- did he mischaracterize any of the factual data that he put in his report?

MR. ROGERS: Object to the form.

THE WITNESS: Once again, I'm unable to provide an overall answer to that question.

BY MR. LOPEZ:

Q Did he -- you know that he looked at a number of different tests, right, that he got from looking at the material from -- from Bard's database that he was allowed to look at, right?

EXHIBIT 8

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

- - -

IN RE: BARD IVC FILTERS PRODUCTS LIABILITY LITIGATION	:	NO. MD-15-02641-PHX-DGC

- - -

July 18, 2017

- - -

DO NOT DISCLOSE - SUBJECT TO FURTHER CONFIDENTIALITY REVIEW

Videotaped deposition of MARK W. MORITZ, M.D., taken pursuant to notice, was held at the offices McCarter & English, LLP, 100 Mulberry Street, Newark, New Jersey, beginning at 9:07 a.m., on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

- - -

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would be significant from such a small piece.

Q. But certainly something that you cannot rule out?

A. I cannot rule it out.

Q. And certainly that would be one reason to consider anticoagulation medication for her?

A. Well, I think that's his logic, but I don't agree with it.

Q. Well, setting aside whether it's his logic, Doris Jones has got a fractured filter in her pulmonary artery, and I think you and I can leave here today agreeing that's a bad thing medically, fair?

MR. BROWN: Object to the form.

THE WITNESS: Correct.

BY MR. O'CONNOR:

Q. And certainly we can agree that Doris Jones deserves and is entitled to every chance she can to be safe from that fragment, correct?

A. Correct.
Q. And certainly something that if she were your patient, you would agree and that if you're consulted with a doctor from another discipline, you would be open to any suggestion that doctor had to protect Doris Jones and give her every opportunity, every chance to survive from this failure that's exposing her to harm?
MR. BROWN: Object to the form.
THE WITNESS: I agree.
BY MR. O'CONNOR:
Q. And Doris Jones is exposed to harm every day that fragment is with her, true?
MR. BROWN: Object to the form.
THE WITNESS: A very small amount.
BY MR. O'CONNOR:
Q. But that can change at any moment?
MR. BROWN: Object to the

form.

THE WITNESS: It can change.

BY MR. O'CONNOR:

Q. You agree with that?

A. Yes.

Q. All the more reason you believe that she should see her doctor often?

A. How often is a question. What do you mean by often? I think once a year would be often enough.

Q. Or more if her doctor or another doctor thinks that's a good idea?

MR. BROWN: Object to the form.

THE WITNESS: If her doctor thinks he needs to see her more, then I would have to agree with that.

BY MR. O'CONNOR:

Q. Can you envision a scenario where that fractured filter caused her symptoms in her chest?

A. I can envision a scenario

what risk.

BY MR. O'CONNOR:

Q. But anytime a patient goes -- undergoes any type of surgery, especially a surgery to a blood vessel, as a vascular surgeon, that is risky?

A. It has risks.

Q. And certainly risks that you really have to weigh when you have a patient like Doris that's presenting with this foreign body in such a critical part of her anatomy, fair?

A. Correct.

Q. Okay. Any other opinions in your report on Doris Jones that we haven't talked about?

You talk about ongoing monitoring. Do you agree it's a good idea that she receives imaging just to monitor to see if that fragment has moved?

A. Yes, I do.

Q. So she should undergo CT imaging?

A. No.
Q. What should she go?
A. CT imaging is a very large dose of radiation. And people who have that are accumulating unnecessary radiation for something like this. I think a plain chest x-ray would be adequate.
Q. At least on a yearly basis?
A. Yes.
Q. And maybe more if necessary?
A. If necessary. But I think not.
Q. Because of her other medical conditions, she is even placed at more risk to undergo a surgery or an attempt to remove this, correct?
A. I'm not sure if it's because of her other medical conditions or because of the method of attachment in the pulmonary artery. I can't make that decision.
Q. Okay. So the way it's attached to the artery may be a reason

not to undergo the procedure?
A. Right. Also, you have to traverse the heart chambers to do it. And the fragment can get caught in the heart chambers theoretically. Once again, I'm not an interventional radiologist, so I don't want to give a more detailed opinion on that.
Q. And just so you and I are on the same page here today, she's got a foreign body in a very critical vessel, and that alone exposes her to risks of complication of risks of harm, correct?
MR. BROWN: Object to the form.
THE WITNESS: Small risk.
BY MR. O'CONNOR:
Q. But risk, albeit?
A. Risk.
Q. And risk that you agree could change at any moment anytime?
MR. BROWN: Object to the form.
THE WITNESS: Yes.